From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]

Sent: 9/26/2016 9:02:33 PM

To: Guilaran, Yu-Ting [Guilaran.Yu-Ting@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Vogel, Dana

[Vogel.Dana@epa.gov]

CC: Arrington, Linda [Arrington.Linda@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Piansay, Maria

[Piansay.Maria@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Davis, Kable

[Davis.Kable@epa.gov]; Smith, Charles [Smith.Charles@epa.gov]; Miller, David [miller.davidj@epa.gov]; Rosenblatt,

Daniel [Rosenblatt.Dan@epa.gov]

Subject: FW: Pet product overview

Attachments: Pet Collars.docx

To inform the decision going forward, Julie and Bo pulled the following information from OPPIN to scope out the universe of spot-on products, collars and "other" pet products. If the OPPIN search is correct, the universe of collars is only 24 registered products.

From: Breeden-Alemi, Julie

Sent: Monday, September 26, 2016 4:46 PM

To: Echeverria, Marietta < Echeverria. Marietta@epa.gov>

Cc: Davis, Kable < Davis.Kable@epa.gov>

Subject: Pet product overview

Here is an estimated overview of pet products:

In July of 2016 it was estimated that there were 880 conventional active dog and cat products. There are approximately 162 registration numbers for spot-ons and 24 registration numbers for collars. The number of products unaccounted for would include products such as dips, sprays, dusts, and shampoos. Keep in mind also that there are several actions inhouse that could change these estimations.

Spot-ons:

162 Registration Numbers

29 Companies

Al's listed include: fipronil, demiditraz, imidacloprid, pyriproxyfen, permethrin, S-methoprene, cyphenothrin, etofenprox, phenothrin, piperonyl butoxide, MGK 264, novaluron, amitraz, spinetroram, indoxacarb, dinotefuran, acetamiprid

Collars (see attached Word document):

24 Registration Numbers

12 Companies

Al's listed: amitraz, pyriproxyfen, gardona (cis-isomer), S-methoprene, flumethrin, imidacloprid, piperonyl butoxide, deltamethrin

From: Echeverria, Marietta [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=36C56B7169144626BD6AADEA25992D4E-MARIETTA ECHEVERRIA]

Sent: 8/8/2016 2:38:51 PM
To: natalie.lamarche@canada.ca

CC: Goodis, Michael [Goodis.Michael@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; Sterkenburg, Neilda (HC/SC)

[neilda.sterkenburg@canada.ca]

Subject: FW: Draft of the pyriofenone chronic bee study

Hi Natalie,

Regarding the flumethrin/imidacloprid pet collar topic we have a conference call currently scheduled for this week on August 10th at 2:30. We will loop back with Peter and Mike following our call.

Thank you, Marietta

From: Goodis, Michael

Sent: Saturday, August 06, 2016 11:56 AM

To: Echeverria, Marietta < Echeverria. Marietta@epa.gov> **Subject:** FW: Draft of the pyriofenone chronic bee study

Marietta

Does this date work or do you or suggest another one? Please contact them directly and copy me...thanks

Michael L. Goodis, P.E.
Acting Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157 Room \$7624

From: Lamarche, Natalie (HC/SC) [mailto:natalie.lamarche@canada.ca]

Sent: Friday, August 05, 2016 1:24 PM

To: Goodis, Michael < Goodis. Michael@epa.gov>

Subject: RE: Draft of the pyriofenone chronic bee study

Hi Michael,

Peter asked me to book a meeting with you for middle of August. Would you be available to meet on Tuesday August 16th from 1 to 2 pm?

Please advise.

Thank you, Natalie for, Peter Brander



Health Canada Santé Canada Canadä

From: Brander, Peter (HC/SC) **Sent:** 2016-07-26 4:42 PM

To: Goodis, Michael

Cc: Hart, Connie (HC/SC); Silva, Minoli (HC/SC); O'Reilly, Joanna (HC/SC); Sterkenburg, Neilda (HC/SC); Lamarche,

Natalie (HC/SC)

Subject: RE: Draft of the pyriofenone chronic bee study

Thank you Michael – just wanted to give you a heads up that I will be away on duty travel for the remainder of the week and then on annual leave until

August 15th.

In my absence, should you agree that it would be of value to have our evaluators discuss the science further, I would ask that you contact Connie Hart, who I have copied on this email. Connie is aware of the file and would be able to assist in pulling together the HC participants for such a discussion.

I was also wondering if we could look to book a meeting for mid-August as a follow-up to the recent discussion between PMRA and the EPA with regard to the review of flumethrin/imidicloprid pet collars. The PMRA had committed to a follow-up meeting with the EPA once we had met with Bayer on this file. I will look to have my EA book this meeting for mid August.

Thank you.

Peter J Brander

Chief Registrar and Director General, Pest Management Regulatory Agency Health Canada / Government of Canada peter.brander@canada.ca / Tel: 613-736-3704

Chef de l'homologation et Directeur général, Agence de réglementation de la lutte antiparasitaire Sante Canada / Gouvernement du Canada peter.brander@canada.ca / Tél : 613-736-3704

From: Goodis, Michael [mailto:Goodis.Michael@epa.gov]

Sent: 2016-07-25 12:11 PM **To:** Brander, Peter (HC/SC)

Subject: RE: Draft of the pyriofenone chronic bee study

Hi Peter

Just letting you know that I got your voicemail and we are looking into it.

I will be in touch when we find out....

Michael L. Goodis, P.E.
Acting Deputy Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Phone 703-308-8157 Room S7624 From: Goodis, Michael

Sent: Tuesday, July 19, 2016 5:29 PM

To: 'Brander, Peter (HC/SC)' < peter.brander@canada.ca>

Cc: Lewis, Susan < Lewis. Susan@epa.gov>

Subject: FW: Draft of the pyriofenone chronic bee study

Hi Peter

Attached is the study review that we discussed. Let me know when you are ready to discuss again.

Michael L. Goodis, P.E. Acting Deputy Director, Registration Division (RD) Office of Pesticide Programs (OPP)

Phone 703-308-8157 Room 57624

From: McCall, Deborah

Sent: Tuesday, July 19, 2016 4:23 PM

To: Goodis, Michael < Goodis. Michael @epa.gov > **Subject:** Draft of the pyriofenone chronic bee study

Attached is the draft copy of the pyriofenone chronic bee study.

Deborah McCall (Debbie)
Chief, Invertebrate & Vertebrate Branch 2
USEPA
Office of Pesticide Programs
1200 Pennsylvania Ave., NW (7505P)
Washington, DC 20460
703.605.0717
mccall.deborah @epa.gov

From: VA-PYS-7971-M@epa.gov [mailto:VA-PYS-7971-M@epa.gov]

Sent: Tuesday, July 19, 2016 4:25 PM

To: McCall, Deborah < McCall. Deborah@epa.gov>

Subject:

From: Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]

Sent: 7/26/2016 9:46:17 PM

To: Goodis, Michael [Goodis.Michael@epa.gov]

Subject: RE: Draft of the pyriofenone chronic bee study

Mike - excellent. Thanks.

Concerning the collar piece – I'd suggest we delegate that to the lead BC's. Imidacloprid is with Meredith and the other one is with Marietta. Might be something else to mention tomorrow at staff.

From: Goodis, Michael

Sent: Tuesday, July 26, 2016 5:30 PM

To: Brander, Peter (HC/SC) <peter.brander@canada.ca>

Cc: Hart, Connie (HC/SC) <connie.hart@canada.ca>; Silva, Minoli (HC/SC) <minoli.silva@canada.ca>; O'Reilly, Joanna (HC/SC) <joanna.oreilly@canada.ca>; Sterkenburg, Neilda (HC/SC) <neilda.sterkenburg@canada.ca>; Lamarche, Natalie (HC/SC) <natalie.lamarche@canada.ca>; Cowles, James <Cowles.James@epa.gov>; Rosenblatt, Daniel

<Rosenblatt.Dan@epa.gov>

Subject: RE: Draft of the pyriofenone chronic bee study

Hi Peter

Thanks for the heads up. I expect we will need to have some type of follow-up discussion among the scientists on this bee study so I will contact Connie to help set it up when ready.

Regarding a meeting on the review of flumethrin/imidicloprid pet collars, let me get back to you to confirm but I would expect a meeting in mid August will work.

Michael L. Goodis, P.E. Acting Deputy Director, Registration Division (RD) Office of Pesticide Programs (OPP)

Phone 703-308-8157 Room S7624

From: Brander, Peter (HC/SC) [mailto:peter.brander@canada.ca]

Sent: Tuesday, July 26, 2016 4:42 PM

To: Goodis, Michael < Goodis. Michael @epa.gov>

Cc: Hart, Connie (HC/SC) <<u>connie.hart@canada.ca</u>>; Silva, Minoli (HC/SC) <<u>minoli.silva@canada.ca</u>>; O'Reilly, Joanna (HC/SC) <<u>joanna.oreilly@canada.ca</u>>; Sterkenburg, Neilda (HC/SC) <<u>neilda.sterkenburg@canada.ca</u>>; Lamarche, Natalie

(HC/SC) <natalie.lamarche@canada.ca>

Subject: RE: Draft of the pyriofenone chronic bee study

Thank you Michael – just wanted to give you a heads up that I will be away on duty travel for the remainder of the week and then on annual leave until August 15th.

In my absence, should you agree that it would be of value to have our evaluators discuss the science further, I would ask that you contact Connie Hart, who I have copied on this email. Connie is aware of the file and would be able to assist in pulling together the HC participants for such a discussion.

I was also wondering if we could look to book a meeting for mid-August as a follow-up to the recent discussion between PMRA and the EPA with regard to the review of flumethrin/imidicloprid pet collars. The PMRA had committed to a follow-up meeting with the EPA once we had met with Bayer on this file. I will look to have my EA book this meeting for mid August.

Thank you.

Peter J Brander

Chief Registrar and Director General, Pest Management Regulatory Agency Health Canada / Government of Canada peter.brander@canada.ca / Tel: 613-736-3704

Chef de l'homologation et Directeur général, Agence de réglementation de la lutte antiparasitaire Sante Canada / Gouvernement du Canada peter.brander@canada.ca / Tél : 613-736-3704

From: Goodis, Michael [mailto:Goodis.Michael@epa.gov]

Sent: 2016-07-25 12:11 PM **To:** Brander, Peter (HC/SC)

Subject: RE: Draft of the pyriofenone chronic bee study

Hi Peter

Just letting you know that I got your voicemail and we are looking into it. I will be in touch when we find out....

Michael L. Goodis, P.E. Acting Deputy Director, Registration Division (RD) Office of Pesticide Programs (OPP)

Phone 703-308-8157 Room \$7624

From: Goodis, Michael

Sent: Tuesday, July 19, 2016 5:29 PM

To: 'Brander, Peter (HC/SC)' peter.brander@canada.ca>

Cc: Lewis, Susan < Lewis. Susan@epa.gov>

Subject: FW: Draft of the pyriofenone chronic bee study

Hi Peter

Attached is the study review that we discussed. Let me know when you are ready to discuss again.

Michael L. Goodis, P.E. Acting Deputy Director, Registration Division (RD) Office of Pesticide Programs (OPP)

Phone 703-308-8157 Room S7624 From: McCall, Deborah

Sent: Tuesday, July 19, 2016 4:23 PM

To: Goodis, Michael < Goodis. Michael @epa.gov > **Subject:** Draft of the pyriofenone chronic bee study

Attached is the draft copy of the pyriofenone chronic bee study.

Deborah McCall (Debbie)
Chief, Invertebrate & Vertebrate Branch 2
USEPA
Office of Pesticide Programs
1200 Pennsylvania Ave., NW (7505P)
Washington, DC 20460
703.605.0717
mccall.deborah @epa.gov

From: VA-PYS-7971-M@epa.gov [mailto:VA-PYS-7971-M@epa.gov]

Sent: Tuesday, July 19, 2016 4:25 PM

To: McCall, Deborah < McCall. Deborah@epa.gov>

Subject:

From: Kaiser, Sven-Erik [Kaiser.Sven-Erik@epa.gov]

Sent: 3/18/2021 6:55:05 PM

To: Richmond, Jonah [Richmond.Jonah@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Dinkins, Darlene

[Dinkins.Darlene@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]; Goodis, Michael

[Goodis.Michael@epa.gov]; Cyran, Carissa [Cyran.Carissa@epa.gov]

Subject: CRS Inquiry regarding Seresto flea and tick collars

Pet Collar Team – please see the request below from the Congressional Research Service asking about Seresto pet collars on behalf of an unnamed member. This is in addition to the Sanders and Krishnamoorti letters. I'm thinking we can reply to CRS by email at the same time that we reply to the other Seresto inquiries. Thanks, Sven

Sven-Erik Kaiser
Office of Congressional and Intergovernmental Relations
U.S. Environmental Protection Agency
202-566-2753
kaiser.sven-erik@epa.gov

From: Yen, Jerry <JYEN@crs.loc.gov>Sent: Wednesday, March 17, 2021 4:58 PMTo: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>Subject: Inquiry regarding Seresto flea and tick collars

Hi Sven,

I hope you are doing well. A requestor recently came across the <u>USA Today reporting on Seresto flea and tick collars</u> and asked me to help "get a status update from EPA on how [the agency] plan[s] to respond to the influx of incident reports submitted regarding use of the Seresto flea and tick collar." The requestor also asked for "any additional data on the recent incidents," such as a breakout regarding the severity of the incidents and any additional information beyond the agency's public responses. When I asked if there was a desired timeframe for a response, the requestor indicated that there wasn't a timeframe, just whenever the agency has an update.

In providing some background information to the staffer, I pointed out excerpts in the February 2020 proposed interim registration review decision for imidacloprid and March 2020 interim registration review decision for flumethrin, that acknowledged the agency is aware of multiple human and pet incidents potentially associated with use of the flea and tick collars. I also mentioned that the agency evaluates and synthesizes multiple sources of information, including incident data, to inform the registration review decision, and that the evaluations of such information are accessible in dockets on regulations.gov.

I hope that you'll find this request straightforward. If you have any questions about the inquiry, just let me know. I appreciate your help and look forward to the response from the agency, that I will then relay to the requestor.

Best Regards,

Jerry Yen, Ph.D. Analyst in Environmental Policy Congressional Research Service Library of Congress jyen@crs.loc.gov This information is intended only for the congressional addressee or other individual to whom it is sent and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of this information is only at the discretion of the intended recipient. If you received this in error, please contact me and delete the material from any computer.

From: Aubee, Catherine [Aubee.Catherine@epa.gov]

Sent: 6/26/2019 5:21:52 PM

To: Mastrota, Nicholas [Mastrota.Nicholas@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]; Biscoe, Melanie

[Biscoe.Melanie@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]

Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

Hi Nick,

Thank you for sharing your thoughts.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

I would encourage you to consider a developmental assignment in RD if you are interested in learning more about the FIFRA labels and review process for these types of products. Quite a bit of work goes into ensuring that labels are clear and that products are supported by experimental data for both efficacy and companion animal safety prior to being registered. There is no lack of expertise in label writing. What is missing is a scientific explanation for why reports of certain effects are occurring, and if they are ubiquitous observations or associated primarily with specific products.

We take the responsibility of regulating these products very seriously, and I appreciate the work of the incident review team in helping to inform our decisions.

Kind regards, Catherine

From: Mastrota, Nicholas

Sent: Wednesday, June 26, 2019 12:26 PM

To: Miller, Robert <Miller.Robert@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Biscoe, Melanie

<Biscoe.Melanie@epa.gov>; Rossmeisl, Colleen <Rossmeisl.Colleen@epa.gov>

Subject: RE: New Tier 2 Incident: flumethrin, imidacloprid

After much thought on this issue, my opinion i

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Nick

From: Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]

Sent: 6/26/2019 1:15:35 PM

To: Miller, Robert [Miller.Robert@epa.gov]

Subject: Automatic reply: New Tier 2 Incident: flumethrin, imidacloprid

I am out of the office on extended leave until August 5th. For assistance please contact one of the following people:

Venus Eagle (eagle.venus@epa.gov) for PM 1 questions Gene Benbow (benbow.gene@epa.gov) for PM 7 questions Catherine Aubee (aubee.catherine@epa.gov) for PM 3 questions

From: Kang, Ji Yeon [Kang.Joyce@epa.gov]

Sent: 1/27/2021 4:45:14 PM

To: Smith, Kimberly [Smith.Kimberly@epa.gov]
CC: Miller, Robert [Miller.Robert@epa.gov]
Subject: RE: Incident Report for 11556-155

Attachments: 11556-155 AggregateSummary Mar 2012-Present.xls

I am sorry.

I forgot about aggregate summaries.

Best,

joyce

From: Smith, Kimberly <Smith.Kimberly@epa.gov>
Sent: Wednesday, January 27, 2021 11:23 AM
To: Kang, Ji Yeon <Kang.Joyce@epa.gov>
Cc: Miller, Robert <Miller.Robert@epa.gov>
Subject: RE: Incident Report for 11556-155

Thank you.

From: Kang, Ji Yeon < Kang. Joyce@epa.gov>
Sent: Wednesday, January 27, 2021 11:00 AM
To: Smith, Kimberly < Smith. Kimberly@epa.gov>
Cc: Miller, Robert < Miller. Robert@epa.gov>
Subject: RE: Incident Report for 11556-155

Here is the report.

Best,

Joyce

From: Smith, Kimberly < Smith.Kimberly@epa.gov>
Sent: Wednesday, January 27, 2021 10:52 AM
To: Kang, Ji Yeon < Kang.Joyce@epa.gov>
Cc: Miller, Robert < Miller.Robert@epa.gov>
Subject: RE: Incident Report for 11556-155

I just sent it. It's March 2012 - Present

From: Kang, Ji Yeon < Kang_Joyce@epa_gov
Sent: Wednesday, January 27, 2021 10:51 AM
To: Smith, Kimberly < Smith, Kimberly@epa_gov
Cc: Miller, Robert < Miller, Robert@epa_gov
Subject: RE: Incident Report for 11556-155

I guess you missed my first e-mail.

I need date range to make a report.
Please let me know, and I will send you the report asap.

Best,

Joyce

From: Kang, Ji Yeon

Sent: Wednesday, January 27, 2021 10:25 AM **To:** Smith, Kimberly < Smith, Kimberly@epa.gov > **Subject:** RE: Incident Report for 11556-155

Good morning,

Can you tell me what is the date range?

Thank you,

Joyce

From: Smith, Kimberly <Smith.Kimberly@epa.gov>
Sent: Wednesday, January 27, 2021 10:22 AM
To: Kang, Ji Yeon <Kang.Joyce@epa.gov>
Cc: Miller, Robert <Miller, Robert@epa.gov>
Subject: Incident Report for 11556-155

Hi Joyce:

Since Bob is out of the office today, I am wondering if you are able to run an incident report for the above registration for animal and human, all levels of severity. Please let me know as soon as possible.

Kimberly

Kimberly Smith Branch Chief, U.S. EPA/OPP/RD PH: 703-305-6434

From: Kang, Ji Yeon [Kang.Joyce@epa.gov]

Sent: 1/27/2021 3:59:48 PM

To: Smith, Kimberly [Smith.Kimberly@epa.gov]
CC: Miller, Robert [Miller.Robert@epa.gov]
Subject: RE: Incident Report for 11556-155

Attachments: 11556-155 Incident Reports Mar 2012-Present.xls

Here is the report.

Best,

Joyce

From: Smith, Kimberly <Smith.Kimberly@epa.gov>
Sent: Wednesday, January 27, 2021 10:52 AM
To: Kang, Ji Yeon <Kang.Joyce@epa.gov>
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Best,

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Good morning,

Can you tell me what is the date range?

Thank you,

Joyce

From: Smith, Kimberly <<u>Smith.Kimberly@epa.gov</u>>
Sent: Wednesday, January 27, 2021 10:22 AM
To: Kang, Ji Yeon <<u>Kang.Joyce@epa.gov</u>>
Cc: Miller, Robert <<u>Miller.Robert@epa.gov</u>>

Subject: Incident Report for 11556-155

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Kimberly

Kimberly Smith Branch Chief, U.S. EPA/OPP/RD PH: 703-305-6434

From: Rivera-Lupianez, Ana [Rivera-Lupianez.Ana@epa.gov]

Sent: 6/6/2017 5:14:51 PM

To: Chen, Jonathan [Chen.Jonathan@epa.gov]; Ciarlo, Timothy [Ciarlo.Timothy@epa.gov]; Crowley, Matthew

[Crowley.Matthew@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]; Panger, Melissa [Panger.Melissa@epa.gov]; Rivera-Lupianez, Ana [Rivera-Lupianez.Ana@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Sell, Nathan

[Sell.Nathan@epa.gov]; Tanner, Lee [Tanner.Lee@epa.gov]

CC: Hopkins, Yvette [Hopkins. Yvette@epa.gov]; Miller, Robert [Miller. Robert@epa.gov]; Dumas, Richard

[Dumas.Richard@epa.gov]

Subject: FW: Noteworthy Case from NPIC - Soresto flea collar

Attachments: 2017-4380.pdf

A soresto (flumethrin and imidacloprid) flea collar incident in SC.

Thanks, Ana

From: Hallman, Amy S [mailto:Amy.Hallman@oregonstate.edu]

Sent: Tuesday, June 06, 2017 12:05 PM

To: Rivera-Lupianez, Ana <Rivera-Lupianez.Ana@epa.gov>
Cc: Jenkins, Jeffrey James <Jeffrey.Jenkins@oregonstate.edu>
Subject: Noteworthy Case from NPIC - Soresto flea collar

Hi Ana,

We had a Soresto Flea Collar incident reported recently.

Case #4380: A veterinarian reported a dog experienced lethargy and incoordination after a Soresto Flea Collar (flumethrin and imidacloprid) was applied off and on for two months.

Thanks, Amy

Amy Hallman, MS
Project Coordinator
National Pesticide Information Center
Oregon State University
Department of Environmental and Molecular Toxicology
amy.hallman@oregonstate.edu
541-737-6093

From: Report.Pesticide.Incident [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=332E2952E851443AA9BF5B0A420206C2-REPORT.PEST]

Sent: 3/10/2021 2:55:22 PM

To: Kang, Ji Yeon [Kang.Joyce@epa.gov]
Subject: FW: Soresto dog collar complaint

Robert A. Miller 6(a)(2) Coordinator U.S. EPA/OPP/RD/ISB (703) 347-8012

From: Rust, Mary <Rust.Mary@epa.gov>
Sent: Wednesday, March 03, 2021 1:13 PM

To: Report.Pesticide.Incident <Report.Pesticide.Incident@epa.gov>

Subject: RE: Soresto dog collar complaint

Thanks. This just is so sad. I will get them our response.

From: Report.Pesticide.Incident < Report.Pesticide.Incident@epa.gov>

Sent: Wednesday, March 03, 2021 1:12 PM
To: Rust, Mary < Rust Mary@epa.gov>
Cc: Picone, Kaitlin < Picone Kaitlin@epa.gov>
Subject: FW: Soresto dog collar complaint

And another.

Robert A. Miller 6(a)(2) Coordinator U.S. EPA/OPP/RD/ISB (703) 347-8012

From: Kristin Pember <kpember10@gmail.com>

Sent: Tuesday, March 02, 2021 1:54 PM

To: Report.Pesticide.Incident < Report.Pesticide.Incident@epa.gov >

Subject: Soresto dog collar complaint

12 yr old border collie/terrier mix

Symptoms: vomiting, gastrointestinal issues, stopped eating, eventually neurological issues which included paralysis starting with his back legs then all four legs and eventually death all within an 8 month period. He was a healthy 12 yr. old with full of life. He had ABSOLUTELY no issues until I put this collar on him and before I put two and two together it was too late. I rescued him at the age of two and now I feel to blame for his death. This is ethically and morally wrong what these pesticides are doing to our pets and what the long terms effects are to our own health. This product needs to be addressed ASAP!!

Pesticide: Soresto (imidacloprid and flumethrin)



Cyran, Carissa [Cyran.Carissa@epa.gov] From:

4/14/2021 4:43:26 PM Sent:

To: Vogel, Dana [Vogel.Dana@epa.gov]; Akerman, Gregory [Akerman.Gregory@epa.gov]; Wilbur, Donald

> [Wilbur.Donald@epa.gov]; Reaves, Elissa [Reaves.Elissa@epa.gov]; Kiely, Timothy [Kiely.Timothy@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rosenblatt, Daniel

[Rosenblatt.Dan@epa.gov]

CC: Overbey, Dian [Overbey.Dian@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]; Smith, Kimberly

[Smith.Kimberly@epa.gov]; Julia Valentine [valentine.julia@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Britton,

Cathryn [Britton.Cathryn@epa.gov]; Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Louie-Juzwiak, Rosanna [Louie-

Juzwiak.Rosanna@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Niman, Aaron [niman.aaron@epa.gov];

Fletcher, Rachel [fletcher.rachel@epa.gov]; Britton, Wade [Britton.Wade@epa.gov]

Subject: FOR PRD/HED/RD DD REVIEW: FDA request to review their flea and tick web page; DDL: 10:00 AM TOMORROW

High Importance:

<!--[if Ite mso 15 || CheckWebRef]-->

Cyran, Carissa has shared a OneDrive for Business file with you. To view it, click the link below.



CU-Flea-Tick-Products 2021-for-EPA-review-21-04-07.docx



<!--[endif]-->

Hello,

We have been asked by FDA to review an outdated article that is on their currently on our web site. The previous version was published in 2014 and focused more on the pyrethrin/permethrin products. FDA has now revised the web page (word file attached and linked) to be a high-level piece encouraging pet owners to work with their veterinarians to select the appropriate product for their situation, use products safely, be aware of the potential for adverse events, and to report these to the regulating agency if they occur.

Staff have reviewed and provided comments/edits, all in track changes. Can you please review and provide any comments edits by 10:00 am tomorrow?

Once you have reviewed, I will send this forward for OPP IO and OCSPP IO approval.

Thank you,

Carissa

Carissa Cyran Communications Branch Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency Phone: (703) 347-8619 (Pronouns: she/her/hers)

From: DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>

Sent: Wednesday, April 7, 2021 11:49 AM

To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>

Cc: Overbey, Dian < Overbey. Dian@epa.gov>; Norris, Anne < Anne. Norris@fda.hhs.gov>

Subject: RE: [EXTERNAL] FW: FDA request for assistance with messaging about regulatory jurisdiction over flea and tick

collars (re: Seresto)

Good morning all,

As part of our outreach on flea and tick products, we've revised an outdated article that is currently on our web site and invite your review and input. The previous version was published in 2014 and focused more on the pyrethrin/permethrin products. We have revised this to be a high-level piece encouraging pet owners to work with their veterinarians to select the appropriate product for their situation, use products safely, be aware of the potential for adverse events, and to report these to the regulating agency if they occur.

Could you all review and add language you feel is appropriate for EPA's evaluation and registration of these products? Or let us know if you would like us to point to a companion piece on your web site?

Would it be possible to receive your comments back by <u>next Friday, April 16</u>? Please let me know if you need additional time.

Thanks so much,

Siobhan DeLancey, RVT, MPH (She/Her/Hers)
Senior Advisor for Strategic Initiatives Center for Veterinary Medicine
U.S. Food and Drug Administration
O: 240-402-9973
M: 202-510-4177
Siobhan.DeLancey@fda.hhs.gov

From: Aubee, Catherine [Aubee.Catherine@epa.gov]

Sent: 4/15/2021 2:59:54 PM

To: Vogel, Dana [Vogel.Dana@epa.gov]; Cyran, Carissa [Cyran.Carissa@epa.gov]; Reaves, Elissa

[Reaves.Elissa@epa.gov]; Akerman, Gregory [Akerman.Gregory@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]; Kiely, Timothy [Kiely.Timothy@epa.gov]; Echeverria, Marietta

[Echeverria.Marietta@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]

CC: Overbey, Dian [Overbey.Dian@epa.gov]; Miller, Robert [Miller.Robert@epa.gov]; Smith, Kimberly

[Smith.Kimberly@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Evans, Elizabeth [Evans.Elizabeth@epa.gov]; Louie-Juzwiak, Rosanna [Louie-Juzwiak.Rosanna@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Niman, Aaron [niman.aaron@epa.gov]; Fletcher, Rachel [fletcher.rachel@epa.gov];

Britton, Wade [Britton.Wade@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]

Subject: RE: FOR PRD/HED/RD DD REVIEW: FDA request to review their flea and tick web page; DDL: 10:00 AM TOMORROW

No comments. Thanks for the opportunity to review, and thanks to the teams for their earlier input.

Best,
Catherine
Associate Director
OPP Registration Division
US Environmental Protection Agency

Contact:

Aubee.catherine@epa.gov Mobile: 571.317.4402

From: Vogel, Dana < Vogel.Dana@epa.gov>
Sent: Thursday, April 15, 2021 9:17 AM

To: Cyran, Carissa < Cyran. Carissa@epa.gov>; Reaves, Elissa < Reaves. Elissa@epa.gov>; Akerman, Gregory < Akerman. Gregory@epa.gov>; Wilbur, Donald < Wilbur. Donald@epa.gov>; Kiely, Timothy < Kiely. Timothy @epa.gov>; Aubee, Catherine < Aubee. Catherine@epa.gov>; Echeverria, Marietta < Echeverria. Marietta@epa.gov>; Rosenblatt, Daniel < Rosenblatt. Dan@epa.gov>

Cc: Overbey, Dian <Overbey.Dian@epa.gov>; Miller, Robert <Miller.Robert@epa.gov>; Smith, Kimberly <Smith.Kimberly@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>; Britton, Cathryn <Britton.Cathryn@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Recore, Shanna <Recore.Shanna@epa.gov>; Evans, Elizabeth <Evans.Elizabeth@epa.gov>; Louie-Juzwiak, Rosanna <Louie-Juzwiak.Rosanna@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Britton, Wade <Britton.Wade@epa.gov>; VanAlstine, Julie <VanAlstine.Julie@epa.gov>

Subject: RE: FOR PRD/HED/RD DD REVIEW: FDA request to review their flea and tick web page; DDL: 10:00 AM TOMORROW

No comments from hed.

From: Cyran, Carissa < Cyran. Carissa@epa.gov >

Sent: Thursday, April 15, 2021 8:58 AM

To: Reaves, Elissa Reaves, Elissa@epa.gov">Reaves, Elissa@epa.gov; Vogel, Dana Vogel, Dana@epa.gov; Akerman, Gregory@epa.gov; Wilbur, Donald Wilbur, Timothy@epa.gov; Kiely, Timothy Kiely, Timothy@epa.gov; Rosenblatt, Daniel Rosenblatt, Daniel Rosenblatt, Daniel Rosenblatt, Daniel Rosenblatt.Dan@epa.gov; Rosenblatt, Daniel Rosenblatt.Dan@epa.gov; Rosenblatt, Daniel Rosenblatt.Dan@epa.gov)

Cc: Overbey, Dian < Overbey. Dian@epa.gov >; Miller, Robert < Miller. Robert@epa.gov >; Smith, Kimberly

<<u>Smith.Kimberly@epa.gov</u>>; Miller, David <<u>Miller.DavidJ@epa.gov</u>>; Britton, Cathryn <<u>Britton.Cathryn@epa.gov</u>>; Herrick, Jacquelyn <<u>Herrick.Jacquelyn@epa.gov</u>>; Recore, Shanna <<u>Recore.Shanna@epa.gov</u>>; Evans, Elizabeth <<u>Evans.Elizabeth@epa.gov</u>>; Louie-Juzwiak, Rosanna <<u>Louie-Juzwiak.Rosanna@epa.gov</u>>; Biscoe, Melanie <<u>Biscoe.Melanie@epa.gov</u>>; Niman, Aaron <<u>niman.aaron@epa.gov</u>>; Fletcher, Rachel <<u>fletcher.rachel@epa.gov</u>>; Britton, Wade <<u>Britton.Wade@epa.gov</u>>; VanAlstine, Julie <<u>VanAlstine.Julie@epa.gov</u>> **Subject:** Re: FOR PRD/HED/RD DD REVIEW: FDA request to review their flea and tick web page; DDL: 10:00 AM

Thank you, Elissa. Just a reminder all comments are due by 10:00 am.

Thank you!

TOMORROW

Carissa

From: Reaves, Elissa < Reaves. Elissa @epa.gov > Sent: Wednesday, April 14, 2021 12:59 PM

To: Cyran, Carissa Cyran.Carissa@epa.gov">Cyran, Carissa@epa.gov; Vogel, Dana Vogel, Dana@epa.gov; Akerman, GregoryCyran, Carissa@epa.gov; Wilbur, Donald Wilbur, Donald@epa.gov; Kiely, Timothy Kiely, Timothy@epa.gov; Rosenblatt, Daniel Rosenblatt, Daniel Kiely, Timothy@epa.gov; Rosenblatt, Daniel Kiely, Timothy@epa.gov; Rosenblatt, Daniel Kiely.Timothy@epa.gov; Rosenblatt, Daniel Kiely.Timothy@ep

Cc: Overbey, Dian <<u>Overbey.Dian@epa.gov</u>>; Miller, Robert <<u>Miller.Robert@epa.gov</u>>; Smith, Kimberly <<u>Smith.Kimberly@epa.gov</u>>; Julia Valentine <<u>valentine.julia@epa.gov</u>>; Miller, David <<u>Miller.DavidJ@epa.gov</u>>; Britton, Cathryn <<u>Britton.Cathryn@epa.gov</u>>; Herrick, Jacquelyn <<u>Herrick.Jacquelyn@epa.gov</u>>; Recore, Shanna <<u>Recore.Shanna@epa.gov</u>>; Evans, Elizabeth <<u>Evans.Elizabeth@epa.gov</u>>; Louie-Juzwiak, Rosanna <<u>Louie-Juzwiak.Rosanna@epa.gov</u>>; Biscoe, Melanie <<u>Biscoe.Melanie@epa.gov</u>>; Niman, Aaron <<u>niman.aaron@epa.gov</u>>; Fletcher, Rachel <<u>fletcher.rachel@epa.gov</u>>; Britton, Wade <<u>Britton.Wade@epa.gov</u>>
Subject: RE: FOR PRD/HED/RD DD REVIEW: FDA request to review their flea and tick web page; DDL: 10:00 AM

Subject: RE: FOR PRD/HED/RD DD REVIEW: FDA request to review their flea and tick web page; DDL: 10:00 AM TOMORROW

Just a couple of minor edits. Thanks

Elissa Reaves, Ph.D.
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs
703-305-0312

From: Cyran, Carissa < Cyran. Carissa@epa.gov > Sent: Wednesday, April 14, 2021 12:43 PM

To: Vogel, Dana < Vogel. Dana@epa.gov >; Akerman, Gregory < Akerman. Gregory@epa.gov >; Wilbur, Donald < Wilbur. Donald@epa.gov >; Reaves, Elissa < Reaves. Elissa@epa.gov >; Kiely, Timothy < Kiely. Timothy@epa.gov >; Aubee, Catherine < Aubee. Catherine@epa.gov >; Echeverria, Marietta < Echeverria. Marietta@epa.gov >; Rosenblatt, Daniel < Rosenblatt. Dan@epa.gov >

Cc: Overbey, Dian <<u>Overbey.Dian@epa.gov</u>>; Miller, Robert <<u>Miller.Robert@epa.gov</u>>; Smith, Kimberly <<u>Smith.Kimberly@epa.gov</u>>; Julia Valentine <<u>valentine.julia@epa.gov</u>>; Miller, David <<u>Miller.DavidJ@epa.gov</u>>; Britton, Cathryn <<u>Britton.Cathryn@epa.gov</u>>; Herrick, Jacquelyn <<u>Herrick.Jacquelyn@epa.gov</u>>; Recore, Shanna <<u>Recore.Shanna@epa.gov</u>>; Evans, Elizabeth <<u>Evans.Elizabeth@epa.gov</u>>; Louie-Juzwiak, Rosanna <<u>Louie-Juzwiak.Rosanna@epa.gov</u>>; Biscoe, Melanie <<u>Biscoe.Melanie@epa.gov</u>>; Niman, Aaron <<u>niman.aaron@epa.gov</u>>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Britton, Wade <Britton.Wade@epa.gov>

Subject: FOR PRD/HED/RD DD REVIEW: FDA request to review their flea and tick web page; DDL: 10:00 AM TOMORROW **Importance:** High

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Carissa

Carissa Cyran

Communications Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Phone: (703) 347-8619

(Pronouns: she/her/hers)

From: DeLancey, Siobhan < Siobhan. Delancey@fda.hhs.gov>

Sent: Wednesday, April 7, 2021 11:49 AM

To: Dunton, Cheryl < <u>Dunton.Cheryl@epa.gov</u>>; Siedschlag, Gregory < <u>Siedschlag.Gregory@epa.gov</u>>; Ozmen, Shamus < Ozmen.Shamus@epa.gov>; Cyran, Carissa < Cyran.Carissa@epa.gov>

Cc: Overbey, Dian < Overbey. Dian@epa.gov>; Norris, Anne < Anne. Norris@fda.hhs.gov>

Subject: RE: [EXTERNAL] FW: FDA request for assistance with messaging about regulatory jurisdiction over flea and tick collars (re: Seresto)

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Thanks so much,

Siobhan DeLancey, RVT, MPH

(She/Her/Hers)

Senior Advisor for Strategic Initiatives

Center for Veterinary Medicine U.S. Food and Drug Administration O: 240-402-9973

M: 202-510-4177

Siobhan.DeLancey@fda.hhs.gov